K100967

PERIMETER® C Spinal System
510(k) Summary
August 2011

AUG - 5 2011

I. **Company:**

Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
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Contact:
Brad Sheals
Senior Regulatory Affairs Specialist

II. **Proposed Proprietary Trade Name:** PERIMETER® C Spinal System

III. **Classification Name(s):** Intervertebral Body Fusion Device (Per 21 CFR Section 888.3080); Product Code(s): ODP

IV. **Description:** The PERIMETER® C Spinal System is intended to be used for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. Additionally, the PERIMETER® C Spinal System implants are to be used with autogenous bone graft and implanted via an open, anterior approach. See the package insert for labeling limitations.

The PERIMETER® C Spinal System consists of spacers of various widths and heights, which can be inserted between two cervical vertebral bodies to give support and correction during cervical interbody fusion procedures. Additionally, this implant has six degrees of lordosis and the superior and inferior surfaces of the implant are designed with teeth which interact with the surface of the vertebral endplates to aid in resisting expulsion. The hollow geometry of the implants allows them to be packed with autogenous bone graft and is to be used with supplemental fixation in all procedures.

This device is offered in PEEK-OPTIMA® (i.e., POLYETHERETHERKETONE) with tantalum markers.

Medical grade titanium implants and medical grade PEEK implants may be used together. **Never use titanium or titanium alloy implants with stainless steel in the same construct.**

V. **Indications for Use**: The PERIMETER® C Spinal System is intended to be used for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc who have had six weeks of non-operative treatment. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. Additionally, the PERIMETER® C Spinal System implants are to be used with autogenous bone graft and supplemental fixation and implanted via an open, anterior approach.

VI. Identification of the Legally Marketed Predicate Devices Use to Claim Substantial Equivalence: The design features, materials and indications for use of the PERIMETER® C Spinal System are substantially equivalent to the previously cleared predicate devices (i.e., K073285, S.E. 05/15/2008; K094042, S.E. 06/30/2010 and K100214, S.E. 06/25/2010). The safety and effectiveness of the subject device is adequately supported by documentation within this premarket notification.

VII. Brief Discussion of the Non-Clinical Tests Submitted

For a determination of substantial equivalence, the following non-clinical mechanical tests were performed:

- Static Torsion Testing per ASTM F2077-03
- Static Compression Testing per ASTM F2077-03
- Dynamic Compression Testing per ASTM F2077-03
- Dynamic Torsion Testing per ASTM F2077-03
- Static Compression- Shear per ASTM F2077-03
- Subsidence Testing per ASTM F2267-04
- Expulsion Testing

VIII. Conclusions Drawn from the Non-Clinical Tests

Results of non-clinical mechanical tests and an engineering rationale indicate that the acceptance criteria were met demonstrating substantial equivalence of the subject device to the listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA
% Mr. Brad Sheals
Sr. Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

AUG 5 2011

Re: K100967
Trade/Device Name: PERIMETER® C Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: July 28, 2011
Received: July 29, 2011

Dear Mr. Sheals:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100967

510(k) Number (if known): K100967

Device Name: PERIMETER® C Spinal System

Indications for Use:

The PERIMETER® C Spinal System is intended to be used for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc who have had six weeks of non-operative treatment. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. Additionally, the PERIMETER® C Spinal System implants are to be used with autogenous bone graft and supplemental fixation and implanted via an open, anterior approach.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X__ OR Over-The-Counter Use _____
Per 21 CFR 801.109

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100967